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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,527	07/25/2007	Patricia Barbosa Jurgilas	7714-76656-01	9870

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EXAMINER
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MONSHIPOURI, MARYAM

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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06/19/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,527	<b>Applicant(s)</b> JURGILAS ET AL.	
	<b>Examiner</b> Maryam Monshipouri	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 and 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Applicant's response to restriction filed 5/20/2009 is acknowledged. Applicant elected Group I (claims 1-3 ) with traverse. Claims 4-8, 10-16 are withdrawn as drawn to non-elected invention. Claim 9 is canceled.

In traversal of restriction requirement applicant argues that all inventions of Groups I-IV share a special technical feature, namely therapeutically effective amount of DM43 protein, which in the written opinion of the International Searching Authority has been found to be both novel and non-obvious. Therefore , in view of applicant, all claims should be examined together.

This argument was fully considered but was found **unpersuasive** because firstly, Applicant is reminded that instant examiner is in no way bound by what the International Searching authority determined.

Secondly, claim 1 , in view of instant examiner, is not novel and inventive (see 102(b) rejection below). Thirdly , the examiner maintains that the special technical feature of each of inventions of Groups III-IV is method of treating tumors, central nervous system and osteoarthritis, respectively, rather than therapeutically effective or pharmaceutically acceptable amount of DM43 protein. In Group I invention, method of treating disorders (claim 9) is already canceled and DM43, which is the special technical feature of Group I, is merely utilized in an in vitro assay, which does not even require a therapeutically effective amount. Therefore, it is puzzling as how all inventions of Groups I-IV, as expressed by applicant, share a special technical feature and thereby should be rejoined.

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In conclusion, in view of the response above, in addition to explanations provided previously, restriction is maintained and is hereby made **Final**.

### **DETAILED ACTION**

Claims 1-3 are under examination on the merits. Claims 4-8, 10-16 are withdrawn as drawn to non-elected invention.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Keith et al. (US 2003/0138925, 7/24/2003). Keith teaches a pharmaceutical composition comprising DM43 prior to this invention (see paragraph 0287). Said composition would inherently comprise pharmaceutically acceptable carrier(s).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Liang et al. (US pat. No. 5,866,570, 2/1999). As stated above Keith teaches a pharmaceutical composition comprising a metalloproteinase inhibitor DM43, prior to this invention. Keith however, does not teach a pharmaceutical composition comprising 10-1000 ng/ml of DM43.

Liang teaches typical concentrations of inhibitors utilized to inhibit coallgenase type IV, which is a metalloproteinase (see for example figure 16) in the micromolar range.

At the invention was made it would have been obvious to start with the composition of Keith and adjust the concentration of metalloproteinase therein according to that taught by Liang.

One of ordinary skill in the art is motivated in adjusting the DM43 concentration in the range of 1-1000  $\mu$ M (which inherently is in the range of 10-1000 ng/ml) because Liang teaches that at such concentration the metalloproteinase inhibitors are effective.

Finally, methods of preparing such pharmaceutical composition are merely routine in the prior art assuring one of ordinary skill in the art a reasonable expectation of success in preparing them.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neves-Ferreira et al. "Neves-F" (BBA, 1474, 309-320, 2000). Neves-F teaches a method of inhibition of lethal effects of B. jararaca venom in mice (see figure 8, page 315), in the presence and absence of DM43 injection (administration) and clearly demonstrates that that DM43 lowers hyperalgesic and edematogenic effects of said venom in mice.

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Neves-F does not teach a method of inhibition of metalloproteinases in human cells comprising contacting said cells with an effective amount of DM43, thereby inhibiting said metalloproteinases.

At the time the invention was made it would have been obvious to one of ordinary skill in the art to start with the method of Neves-F and replace the mice of Neves -F with human cells.

One of ordinary skill in the art is motivated in substituting mice of Neves-F with human cells because obviously, one cannot test such venom inhibition in live humans and therefore, human cells is a reasonable alternative to be used for testing the inhibitory effects (antidote effects) of DM43 on metalloproteinases, in humans.

Finally, one of ordinary skill in the art has a reasonable expectation of success in testing the inhibitory effects of DM43 in human cells contacted with said inhibitor because methods of testing the inhibitory effects of antidotes ( including metalloproteinase inhibitors) in human cells are well established in the prior art, rendering the invention obvious.

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

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